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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/495,186	02/01/2000	John McMichael	13024/35946	4501

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EXAMINER
WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/495,186	MCMICHAEL ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's arguments filed 7-9-03, paper number 22, have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 15-19 are pending and under consideration.

Claim Rejections - 35 USC § 112

I. Claims 15-19 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record.

Claim 15 requires treating a patient having pain caused by otitis media comprising the steps of: administering eardrops to the ear of said patient in a manner so as not to effect gene transfer, thereby reducing said pain, wherein said eardrop comprises an effective amount of DNA in a pharmaceutically-acceptable vehicle.

Otitis media is caused by bacteria or viruses in the ear and results in tympanic membrane retraction, bulging, redness and immobilization (Klein of record, 1994, Clinical Infectious Disease, Vol. 19, pg 823-833). Treatment with analgesic and decongestants do not alter the course of the infection, as neither have an effect on the bacteria or virus causing the disease. Thus, the person of skill in the art would conclude that the only management methods for treating otitis media itself, and not just symptoms of otitis media, are those that result in the reduction of bacteria or virus numbers. The prior art taught that even administering placebo to patients having otitis media results in

decreasing the number of bacteria. Dagen of record (1988, Ear, Nose and Throat J., Vol. 77, pg 16-19) taught administering placebo to patients with otitis media caused by *H. influenza* resulted in a decrease in 48% of the bacteria present. Administering placebo to patients with otitis media caused by *S. pneumococcus* resulted in a decrease in 16% of the bacteria present. Examples XX, XXI, XXIV and XXV are directed to the treatment of pain; however, the specification does not evidence in these examples, or elsewhere in the disclosure the reduction in the number of bacteria or virus which cause otitis media. Nor do the examples have controls that teach obtaining results better than a placebo effect. Thus, applicants have not provided evidence of patients receiving treatment results in the decrease in the number of bacteria or virus or that the results obtained are greater than a placebo effect. Furthermore, it is reasonable to assume that the ear of an individual already has DNA in the fluid within the ear as viral and bacterial particles contain DNA. However, the specification does not provide adequate guidance indicating that the minute amount of DNA being added in the eardrop is effecting a change in the symptoms or the amount of pathogen in the ear. Therefore, it would require one of skill undue experimentation to obtain a therapeutic effect against otitis media that is a direct result of administering eardrops containing DNA.

Applicants argue the reduction of bacteria does not necessarily correlate with otitis media and that the treatment of infection is not necessarily sufficient to treat the symptoms of otitis media. Applicant's argument is not persuasive. Applicants provide a definition that states otitis media is caused by viral or bacterial infection and results in inflammation. The definition provided does not state inflammation is not relieved upon

elimination of infection. It cannot be determined how applicants have come to such a conclusion. Applicants have not provided any reference that states inflammation persists in the absence of virus or bacteria. The presence of bacteria/virus does correlate with otitis media and the reduction in virus or bacteria does cause a decrease in inflammation (Dagan of record, pg 16, Introduction; pg 17, "Causative organisms").

II. Claims 15-19 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

The phrase "so as to not effect gene transfer" is indefinite. The common meaning of "effect" is "something brought about by a cause or agent." Therefore, the phrase means a treatment that fails to introduce DNA into the patient. The specification is silent with regards to the metes and bounds of such treatments. It cannot be determined when eardrops cause and do not cause "gene transfer". It cannot be determined that "gene transfer" is limited to transfection means and not merely transferring DNA from the bottle to the patient. As such, the metes and bounds of how the eardrop is administered cannot be determined.

Applicants argue it is clear that "gene transfer" does not relate to transferring DNA from the bottle to the patient. Applicant's argument is not persuasive. The specification is directed toward administering eardrops comprising DNA to patient without transfecting cells. Given the teachings in the specification, administering DNA to a patient in eardrops is gene transfer. Therefore, it is not clear from the specification that "gene transfer" is limited to transfection means.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL WILSON
PRIMARY EXAMINER